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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/001,878	11/19/2001	Rasean L. Hamilton	ACSC 60015 (1906D)	3409

7590

10/22/2003

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EXAMINER
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THANH, LOAN H

ART UNIT	PAPER NUMBER
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3763

DATE MAILED: 10/22/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

10/001,878

Applicant(s)

HAMILTON ET AL.

Examiner

LoAn H. Thanh

Art Unit

3763

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 19 November 2001.
- 2a) ☐ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 20-25 is/are pending in the application.
- 4a) Of the above claim(s) 20 and 21 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 22-25 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 19 November 2001 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☒ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 5.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

## DETAILED ACTION

### *Election/Restrictions*

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 20-21, drawn to a method of forming a distal tip, classified in class 264, subclass 445.
- II. Claims 22-25, drawn to a balloon catheter, classified in class 604, subclass 96.01.

The inventions are distinct, each from the other because of the following reasons:

Inventions II and I are related as process of making and product made. The inventions are distinct if either or both of the following can be shown: (1) that the process as claimed can be used to make other and materially different product or (2) that the product as claimed can be made by another and materially different process (MPEP § 806.05(f)). In the instant case the product made can be made by another materially different process such as by adhesive bonding, extrusion or molding, etc.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

Because these inventions are distinct for the reasons given above and the search required for Group I is not required for Group II, restriction for examination purposes as indicated is proper.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

This application contains claims directed to the following patentably distinct species of the claimed invention:

A/ figs. 1-5

B/ fig. 6

C/ fig. 7

D/ fig. 8.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, no claims are generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include

all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

During a telephone conversation with Gunther Hanke on 10/16/03 a provisional election was made without traverse to prosecute the invention of group II, claims 22-25. Affirmation of this election must be made by applicant in replying to this Office action. Claims 20-21 have been withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

An action on the merits now follows.

***Priority***

This application repeats a substantial portion of prior Application No. 09/471053, filed 12/21/1999, and adds and claims additional disclosure not presented in the prior application. Since this application names an inventor or inventors named in the prior application, it may constitute a continuation-in-part of the prior application. Should applicant desire to obtain the benefit of the filing date of the prior application, attention is directed to 35 U.S.C. 120 and 37 CFR 1.78.

This application has been filed as a division of Application No. 09/471053, filed 12/21/1999. A later application for a distinct or independent invention, carved out of a pending application and disclosing and claiming only subject matter disclosed in an earlier or parent application is known as a divisional application or "division." The divisional application should set forth only that portion of the earlier disclosure which is germane to the invention as claimed in the divisional application. It appears to the Examiner that the divisional status of this pending application is not proper.

For the purpose of art rejection, the claims have been given the effective filing date of 11/19/01.

The parent application 09/471053 has disclosed only a "sheath ( not shown) located distally adjacent to the distal end of the balloon distal shaft section 27 could be disposed about and secured to the inner tubular member 21 OR tip member 14 in place of the distal end of the balloon distal shaft section 27". The pending application 10/001878 has now amended the specification to include a new drawing (fig. 8) and claims the sheath "disposed about and secured to the proximal end of the tip and the

distal end of the catheter shaft ". The amendment not being supported as original disclosed in the parent application which applicant appears to be claiming priority to.

### ***Oath/Declaration***

The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02.

The oath or declaration is defective because:

It does not state that the person making the oath or declaration has reviewed and understands the contents of the specification, including the claims, as amended by any amendment specifically referred to in the oath or declaration.

If in fact applicant is intending to claim priority as a CIP, applicant is required to submit a new oath/declaration acknowledging the amendment filed 11/19/01 and the new drawing of figure 8 which was filed in addition to the original specification.

### ***Information Disclosure Statement***

The information disclosure statement filed 02/01/02 fails to comply with 37 CFR 1.98(a)(2), which requires a legible copy of each foreign patent; each publication or that portion which caused it to be listed; and all other information or that portion which caused it to be listed. It has been placed in the application file, but the information referred to therein has not been considered. Upon resubmitting the documents, the Examiner will consider at the time of the next communication.

### ***Drawings***

The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the balloon on the distal catheter shaft section or the balloon distal shaft section disposed about the catheter shaft must be shown or the feature(s) canceled from the claim(s). No new matter should be entered. It appears that the balloon distal shaft section is only secured to the inner tubular member which is not the same as the catheter shaft since the equivalent of the catheter shaft would be the outer tubular member.

A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

### ***Specification***

The disclosure is objected to because of the following informalities: It is unclear what the amendment filed on page 8 of the preamendment filed 11/19/01 is intending to further disclose. Applicant amended "more preferably about 0.05 to about 0.5mm" and it appears that range has already been disclosed in the same sentence.

Appropriate correction is required.

The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required: Applicant does not have support for the claimed subject



matter of " a sheath which is disposed about and secured to the proximal end of the tip member AND the distal end of the catheter shaft/ inner tubular member" . Applicant is required to put this in the specification to provide proper support for the claimed language since the specification has only disclosure to the "sheath being disposed about and secured to the distal end of the inner tubular member 21 or tip member 14" . See page starting on page 6, line 9 to page 7, line 2.

### ***Claim Objections***

Claims 22-25 are objected to because of the following informalities: In claim 22, Applicant is requested to amend the claimed language in a manner which is consistent and less confusing. Applicant has claimed a elongated catheter shaft and then recites the balloon to be on a distal catheter shaft section. It is unclear whether this distal catheter shaft section of part b/ is a section of the elongated catheter shaft of that in part a/ or whether it is another section . Further , applicant is claiming a tip member in part c/ which is on the distal end of the catheter. It is unclear whether the catheter of part c/ is the same as the elongated catheter or whether it is the balloon catheter of the device which makes it unclear. Further, applicant is requested to be consistent with the "catheter shaft " of part d/ which the Examiner is interpreting as the same as the "elongated catheter shaft" of part a/ .

Applicant is requested to be consistent with the terminologies with claims 23-25 in a similar manner.

In claim 23, it is unclear whether the "catheter shaft " is the same as the "elongated catheter shaft.

Appropriate correction is required.

***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 24 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 24 is vague and indefinite because it lacks proper antecedent basis for "inner tubular member" in line 2 of the claim.

***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 22-25 are rejected under 35 U.S.C. 102(e) as being anticipated by Wantink ( US2003/003292 A1).

Wantink discloses a balloon catheter having an outer and inner tubular member having a guidewire lumen, a balloon 34 having a balloon distal shaft section 73, a tubular tip member 31, and a sheath 100 which is disposed about and secured to the inner tubular shaft (via the distal shaft section of the balloon) and the proximal end of the tubular tip member 31. See figure 3, 4f, 5.

Claims 22-25 are rejected under 35 U.S.C. 102(b) as being anticipated by Fischell et al. ( U.S. Patent No. 5,743,874).

Fischell et al disclose a balloon catheter having a balloon 150 , an outer 140 and inner tubular member 130, inflation lumen, a sheath 180 disposed and secured about the distal end of the inner tubular member 131 and the proximal end of the tubular tip member 110.

### ***Double Patenting***

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 22-25 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-2,7-14 of U.S. Patent No. 6,368,301 B1. Although the conflicting claims are not identical, they are not patentably distinct from each other because the broader recitation of the balloon catheter in pending application would be encompassed by the claims of the patent. Further it would have been obvious to one of ordinary skill in the art in view of prior art admission that it would have been obvious to modify the distal end with a sheath. Thus, if a patent was to grant on the pending claims of this application applicant would be granted an unlawful extension of protection beyond the years of the 6,368,301 B1 patent.

### ***Conclusion***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to LoAn H. Thanh whose telephone number is (703) 305-0038. The examiner can normally be reached on Monday to alternating Fridays (7:00 am-4:30 pm).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Brian Casler can be reached on (703) 308-3552. The fax phone number for the organization where this application or proceeding is assigned is (703) 872-9306.

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Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0858.

A handwritten signature in black ink, appearing to read 'LoAn H. Thanh', written in a cursive style.

LoAn H. Thanh  
Primary Examiner  
Art Unit 3763

LT